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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/404,979	09/22/1999	T. VENKAT GOPAL	GENAPP.002RA	8979

32042 7590 09/10/2003

PATTON BOGGS LLP  
8484 WESTPARK DRIVE  
SUITE 900  
MCLEAN, VA 22102

EXAMINER
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MCKELVEY, TERRY ALAN

ART UNIT	PAPER NUMBER
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1636

31

DATE MAILED: 09/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/404,979

Applicant(s)

GOPAL, T. VENKAT

Examiner

Terry A. McKelvey

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,3,4,6 and 7 is/are allowed.
- 6) ☒ Claim(s) 2,5 and 8-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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**DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 102***

Claims 2, 5, 8, 10-11, and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Woo et al (U.S. Patent No. 5,994,109), and alternatively, under 35 U.S.C. 102(a) as being anticipated by Smith et al (WO 93/18759). This rejection is maintained for reasons of record set forth in Paper No. 28, mailed 12/17/02. Applicants' arguments and the declaration filed 6/16/03 have been fully considered but they are not deemed to be persuasive for the remaining claims specifically set forth in the instant rejection statement.

***Claim Rejections - 35 USC § 103***

Claims 2, 5, 8-11, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Woo et al (U.S. Patent No. 5,994,109) or Smith et al (WO 93/18759), in view of Short (U.S. Patent No. 5,589,392). This rejection is maintained for reasons of record set forth in Paper No. 28, mailed 12/17/02. Applicants' arguments and the declaration filed 6/16/03 have

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been fully considered but they are not deemed to be persuasive for the remaining claims specifically set forth in the instant rejection statement.

Claims 2, 5, 8, and 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Woo et al (U.S. Patent No. 5,994,109) or Smith et al (WO 93/18759), in view of Gorman (U.S. Patent No. 5,024,939). This rejection is maintained for reasons of record set forth in Paper No. 28, mailed 12/17/02. Applicants' arguments and the declaration filed 6/16/03 have been fully considered but they are not deemed to be persuasive for the remaining claims specifically set forth in the instant rejection statement.

#### ***Response to Amendment***

The declaration filed on 6/16/03 under 37 CFR 1.131 is sufficient to overcome the Woo et al and Smith et al references, with regard to claims 1, 3-4, and 6-7 only. The declaration showed that applicant had invented the invention of claims 1, 3-4, and 6-7 by showing reduction to practice (and thus possession) of a species that falls within the scope of claims 1, 3-4, and 6-7 prior to the effective date of the references, and that that species provided an adequate basis for inferring

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that the invention has generic applicability as drawn to claims 1, 3-4, and 6-7, because one would recognize that the species corresponds to the structure as claimed in claim 1, that different basic amino acids could be interchangeably used (claim 3), that different nuclear localization signals known in the art could be interchangeably used (claim 4), that different neutral amino acids could be interchangeably used (claim 6), and that the NLS peptide can be located at either end of the molecule (claim 7).

The declaration filed on 6/16/03 under 37 CFR 1.131 has been considered but is ineffective to overcome the Woo et al and Smith et al references with regard to claims 2, 5, and 8-14.

The evidence submitted is insufficient to establish a reduction to practice of the invention in this country or a NAFTA or WTO member country prior to the effective date of the Woo et al and Smith et al references.

The declaration and evidence filed on 6/16/03 does not show a reduction to practice of the claimed invention drawn to having the following limitations: polymeric chain being within the particular range of 10 to 50 residues (claim 2), that the hinge region is between 6 and 50 amino acid residues (claim 5), that the transfection vector further comprises a cell type-specific

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ligand molecule (claim 8), or that the DNA structural sequence is specifically one selected from certain specific types of sequences (claims 9-14). The specific species described in the declaration and supporting evidence does not provide an adequate basis for inferring that the invention has applicability regarding the additional limitations as claimed because there is nothing about the species that would lead one to infer the claimed invention drawn to the additional limitations of claims 2, 5, and 8-14.

#### ***Response to Arguments***

The applicant argues that the declaration filed 6/16/03 states actual reduction to practice of the Gopal invention before the Woo or Smith reference dates. This argument is persuasive for claims 1, 3-4, and 6-7 only, for the reasons cited above. This argument is not persuasive for claims 2, 5, and 8-14 for the reasons cited above. Therefore, it is proper that the rejections of record are maintained with regards to claims 2, 5, and 8-14.

#### ***Conclusion***

Claims 1, 3-4, and 6-7 are allowed.

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**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 703-872-9306. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO

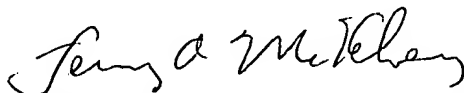
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DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning rejections or other major issues in this communication or earlier communications from the examiner should be directed to Terry A. McKelvey whose telephone number is (703) 305-7213. The examiner can normally be reached on Monday through Friday, except for Wednesdays, from about 7:30 AM to about 6:00 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached on (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
Terry A. McKelvey, Ph.D.  
Primary Examiner  
Art Unit 1636

September 3, 2003